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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/800,770	03/06/2001	Todd M. Kinsella	A-68614-1/RMS/RMK	3911

7590 05/21/2003

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EXAMINER
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WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 05/21/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application N .

09/800,770

Applicant(s)

KINSELLA, TODD M.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☐ Claim(s) 59-87 is/are pending in the application.
- 4a) Of the above claim(s) 62 and 66-87 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 59-61 and 63-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10, 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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#### **DETAILED ACTION**

Applicant's election without traverse of Group III (formerly claims 10-11), now claims 58-86, the species random peptide; GFP and without a fusion partner in Paper No. 17 is acknowledged.

Claims 62 and 66-87 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 17.

#### ***Status of Claims***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 58-86 been renumbered claims 59-87. Claims 1-58 have been cancelled.

Claims 62 and 66-87 have been withdrawn from consideration as being drawn to non-elected invention. [Claims 68-81 are drawn to a library that have been restricted out in the restriction

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requirement of 1/28/03. Newly presented claims 82-87 are drawn to cells which have not been originally presented].

Claims 59-61 and 63-65 are under examination.

***Specification***

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at page 9, line 25. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors [typographical errors (e.g., "ti" in the abstract; closed bracket at page 10, line 26), grammatical and/or idiomatic). Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and

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use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 59-61 and 63-65 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide an adequate description for a claim to any retroviral vectors comprising any first region encoding a fusion polypeptide that generates any cyclic peptide wherein the fusion polypeptide comprises any type of C- and N terminal intein motif with any kind of peptide. The specification presents a generic disclosure for each of the different individual components of the instant claim. Each of the individual components is disclosed as a list present in the prior art. It cannot be ascertained from the separate general description of each of the individual components the picking and choosing that can be made to result in the instant invention. The specific description in the specification i.e., the EXAMPLES, page 59 do not describe any retroviral to which the encoding first region has been transfected therein. It does not

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positively recite for the components present in the claimed retroviral vector. It simply recites a fluorescent reporter system designed for intein cyclization. However, the method by which the system is designed is not positively described.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 59-61 and 63-65 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 59 is indefinite as "a first region" is an arbitrary designation that fails to recite the compound in said region. "Capable" fails to ascertain the claimed invention with precision as to the cyclic peptide that has been generated. The claim is indefinite as to whether the fusion polypeptide generates a cyclic peptide. A peptide cannot generate a cyclic peptide. The term "generating" is not a positive characterization of the vector and relates more to a process

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step. The metes and bounds of the claimed "motif" are unclear as to the kind and length of residues present in the motif.

B). Claim 60 is unclear as to the kind of alteration in the splicing activity made, especially since the base claim does not recite for any altering activity.

C). Claim 61 is unclear as to which peptide in the base claim is a random peptide.

D). Claim 63 is indefinite in the recitation of the arbitrary, relative "second region". It is not clear as to whether the second region is part of the fusion polypeptide recited in the base claim or separately encoded.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 59-61 and 63 are rejected under 35 U.S.C. 102(a) as being anticipated by Scott et al (PNAS).

Scott discloses a vector comprising a nucleic acid that encodes a fusion protein of SSP DNA EIN with intein fragments of In-Target(peptide)-In. See the Materials and methods at page

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13638 up to page 13640. Scott further discloses the use of His-tag (reporter protein, as claimed). Therefore, the specific vector used by Scott comprising of specific inteins and fusion polypeptide with cyclic peptide fully meets the broad claimed retroviral vectors comprising undefined any components therein.

Claims 59-60 and 63 are rejected under 35 U.S.C. 102(a) as being anticipated by Iwai et al (FEBS Letters).

Iwai discloses at page 166 a vector containing a fusion polypeptide with a cyclized polypeptide of  $\beta$ -lactamase with intein ligated thereto. See the detailed description in the Materials and methods section at page 168 up to page 169. Therefore, the broad claimed retroviral vector containing undefined compounds is fully met by Iwai.

Claims 59-61 and 63 are rejected under 35 U.S.C. 102(a) as being anticipated by Evans et al (The Jnl. of Biol. Chem.).

Evans discloses (at page 18359, Experimental Procedures up to page 18360) a retroviral vector. The vector comprises a fusion target protein fused with Ssp intein and Mxe Gyr A which generate a cyclic peptide such as BBP, RGD and CDR. Accordingly, the specific vector of Evans fully meet the broad claimed vector.



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**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A). Patten et al discloses a gene sequences and engineered genetic elements.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T.D. W  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

tdw  
May 16, 2003